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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,333	10/21/2003	Michael R. Hale	VPI99-105DIV	1422
1473 7590 05/14/2007 FISH & NEAVE IP GROUP ROPES & GRAY LLP 1211 AVENUE OF THE AMERICAS NEW YORK, NY 10036-8704			EXAMINER POWERS, FIONA	
			ART UNIT 1626	PAPER NUMBER
			MAIL DATE 05/14/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/691,333

Applicant(s)

HALE ET AL.

Examiner

Fiona T. Powers

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2006 and 13 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-33 is/are pending in the application.
- 4a) Of the above claim(s) 23-27 and 32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-22, 28-31 and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

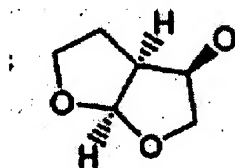
Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 10/21/03, 6/22/06.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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Receipt is acknowledged of the information disclosure statements filed October 21, 2003 and June 22, 2006 and the amendment filed March 13, 2007, which have been entered in the file.

Applicant's election with traverse of Group II, compounds



and compositions where R' is

in the reply filed on July 25, 2006 is acknowledged. Claims 1 to 5, 7 to 22, 28 to 31 and 33 are encompassed by the elected group. The traversal is on the ground(s) that it would not be a serious burden to examine the method claims along with the claims to the compounds and pharmaceutical compositions. This is not found persuasive because for the reasons given in the last office action.

The requirement is still deemed proper and is therefore made FINAL.

Claims 23 to 27 and 32 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on July 25, 2006.

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The first paragraph of the specification concerning the related application should be amended to contain the patent number of the parent application after the filing date (i.e. now U.S. Patent 6,878,728).

The disclosure is objected to because of the following informalities: on page 130, line 11, "29-60" should be -229-260-.

Appropriate correction is required.

Claims 1, 4, 9 and 11 are objected to because of the following informalities: in claims 1 and 9, where the substituent of Q is defined, an "or" should be inserted between " $-N(R^2)R^8$ " and " $-N(R^2)$ -arylalkyl". In claims 4 and 11, and "or" should be inserted between the last two radicals listed.

Appropriate correction is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2 9, 15 to 17, 28 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 1 and 9 define variable R^1 and claim 2 refers to variable R^1 but R^1 does not appear in the formulae nor is it a part of any other variable.

Claims 15 to 17, 28 and 33 refer to compound numbers but the structures of the compounds are not included in the claims.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

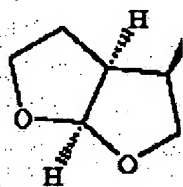
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 to 5, 7 to 22, 28 to 31 and 33 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 to 5 and 18 to 20 of U.S.

Patent No. 6,319,946. Although the conflicting claims are not

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identical, they are not patentably distinct from each other because the claims overlap when in the '946 patent Ht is

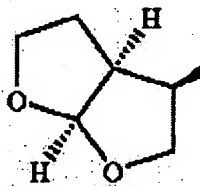



, x is 0 and D is C₁-C₆ alkyl or C₂-C₄ alkenyl that is substituted with Q or C₃-C₆ cycloalkyl optionally substituted with or fused to Q or C₅-C₆ cycloalkenyl optionally substituted with or fused to Q wherein Q contains one substituent selected from OR² or N(R²)₂. The claims of the instant application and the '946 patent differ in that the claims of the patent are broader. The compounds of the instant application and the patent have the same utility as agents for the treatment of HIV infection. One of ordinary skill in the art would have been motivated to make the claimed compounds with the expectation that additional agents for the treatment of HIV infection would be obtained. The claimed compounds would have been rendered obvious by the compounds of the reference in the absence of any unobvious property.

Claims 1 to 5, 7 to 22, 28 to 31 and 33 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4 and 15 to 19 of U.S. Patent No. 6,613,743. Although the conflicting claims are not

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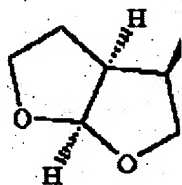
identical, they are not patentably distinct from each other because the claims overlap when in the '743 patent A is $-R^1-Ht$,



R^1 is $-O-C(O)-$, Ht is  and x is 0. The claims of the instant application and the '743 patent differ in that the claims of the patent are broader. The compounds of the instant application and the patent have the same utility as agents for the treatment of HIV infection. One of ordinary skill in the art would have been motivated to make the claimed compounds with the expectation that additional agents for the treatment of HIV infection would be obtained. The claimed compounds would have been rendered obvious by the compounds of the reference in the absence of any unobvious property.

Claims 1 to 5, 7 to 22, 28 to 31 and 33 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 to 7 and 18 to 20 of U.S. Patent No. 6,617,350. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims overlap when in the '350 patent Ht is

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, x is 0 and D is C₁-C₆ alkyl or C₂-C₄ alkenyl that is substituted with Q or C₃-C₆ cycloalkyl optionally substituted with or fused to Q or C₅-C₆ cycloalkenyl optionally substituted with or fused to Q wherein Q contains one substituent selected from OR² or N(R²)₂. The claims of the instant application and the '946 patent differ in that the claims of the patent are broader. The compounds of the instant application and the patent have the same utility as agents for the treatment of HIV infection. One of ordinary skill in the art would have been motivated to make the claimed compounds with the expectation that additional agents for the treatment of HIV infection would be obtained. The claimed compounds would have been rendered obvious by the compounds of the reference in the absence of any unobvious property.

The references made of record and not relied upon show the state of the art.

The closest prior art compounds are disclosed in Baker et al., Bioorganic & Medicinal Chemistry Letters, 8(24), 3631-3636, 1998, Ghosh et al., Bioorganic & Medicinal Chemistry Letters, 8(6), 687-690, 1998 and WO 95/24385. The compounds disclosed

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therein differ from the claimed compounds in that the group that corresponds to D is alkyl that is substituted by Q and Q is phenyl but the phenyl is unsubstituted and the instant claims require that Q be substituted by one substituent selected from OR^2 , OR^8 , O-arylalkyl, SR^8 , S-arylalkyl, $N(R^2)R^8$ and $N(R^2)$ -arylalkyl.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fiona T. Powers whose telephone number is 571-272-0702. The examiner can normally be reached on Monday - Friday 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Fiona T. Powers
Fiona T. Powers
Primary Examiner
Art Unit 1626

ftp
May 10, 2007